



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Johannes Bernardus Mathias Marie van Bree, Edna Henriette Germaine Venneker and David P. Meeker

Application No.: 10/611,598

Group: 1651

Filed: June 30, 2003

Examiner: F.C. Prats

Confirmation No.: 2502

For: TREATMENT OF POMPE'S DISEASE

CERTIFICATE OF MAILING OR TRANSMISSION	
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
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P.O. Box 1450  
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Sir:

This Supplemental Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

06/01/2006 AKELECH 00000026 10611598 180.00 OP  
01 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references are enclosed.
- ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:  
*(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)*

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
 \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
 \_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
 Examiner

\_\_\_\_\_  
 Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: *5/30/06*

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 4064.1000-005	APPLICATION NO. 10/611,598	
SUPPLEMENTAL INFORMON DISCLOSURE STATEMENT IN AN APPLICATION  May 30, 2006 (Use several sheets if necessary)		FIRST NAMED INVENTOR Joannes B.M.M. Van Bree		FILING DATE June 30, 2003
		EXAMINER F.C. Prats	CONFIRMATION NO. 2502	GROUP 1651

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C16	Bijvoet, A.G.A., <i>et al.</i> , "Recombinant Human Acid $\alpha$ -Glucosidase: High Level Production in Mouse Milk, Biochemical Characteristics, Correction of Enzyme Deficiency in GSDII KO Mice," <i>Hum. Mol. Genet.</i> 7(11): 1815024 (1998)
C17	Fuller, M., <i>et al.</i> , "Isolation and Characterisation of a Recombinant, Precursor Form of Lysosomal Acid $\alpha$ -Glucosidase," <i>Eur. J. Biochem.</i> , 234: 903-909 (1995)
C18	Hoefsloot, L.H., <i>et al.</i> , "Primary Structure and Processing of Lysosomal $\alpha$ -Glucosidase; Homology with the Intestinal Sucrase-Isomaltase Complex," <i>EMBO</i> , 7(6); 1697-1704 (1988)
C19	Martiniuk, F., <i>et al.</i> , "Recombinant Human Acid $\alpha$ -Glucosidase Generated in Bacteria: Antigenic, but Enzymatically Inactive," <i>DNA and Cell Biol.</i> 11(9): 701-706 (1992)
C20	Yang, H.W., <i>et al.</i> , "Recombinant Human Acid $\alpha$ -Glucosidase Corrects Acid $\alpha$ -Glucosidase-Deficient Human Fibroblasts, Quail Fibroblasts, and Quail Myoblasts," <i>Pediatr. Res.</i> , 43(3) 374-80 (1998)
C21	Van Hove, J.L.K., <i>et al.</i> , "High-Level Production of Recombinant Human Lysosomal Acid $\alpha$ -Glucosidase in Chinese Hamster Ovary Cells Which Targets to Heart Muscle and Corrects Glycogen Accumulation in Fibroblasts from Patient with Pompe Disease," <i>Proc. Natl. Acad. Sci.</i> 93: 65-70 (1996)
C22	Raben, N., <i>et al.</i> , "Targeted Disruption of the Acid $\alpha$ -Glucosidase Gene in Mice Causes an Illness with Critical Features of Both Infantile and Adult Human Glycogen Storage Disease Type II," <i>J. Biol. Chem.</i> , 272(30): 19086-19092 (1998)

EXAMINER

DATE CONSIDERED